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510(k) Summary of Safety and Effectiveness

General Provisions

The name of the device is:

Proprietary Name	Common or Usual Name
Dorsal Nail Plate™, Anatomical	Plate Fixation Bone

Name of Predicate Devices

The device is substantially equivalent to:

- Dorsal Nail Plate of the Distal Radius Fracture Repair System (510(k) # K023007 – December 5, 2002) – Hand Innovations, Inc.

Classification

Class II.

Performance Standards

Performance standards have not been established by the FDA under section 514 of the Food, Drug and Cosmetic Act.

Indications for Use

The **Dorsal Nail Plate™, Anatomical** is intended for the fixation of fractures and osteotomies involving the distal Radius.

Device Description

The **Dorsal Nail Plate™, Anatomical** is intended to treat fractures in both left and right Radius. The distal segment of the nail plate is intended to be attached to the dorsal surface of the distal Radius. The proximal segment of the nail plate is intended to be inserted into the Radial shaft.

Biocompatibility

The **Dorsal Nail Plate™, Anatomical** do not require biocompatibility testing because the Titanium Alloy used in fabrication meets the requirements of ASTM F 136.

Summary of Substantial Equivalence

The **Dorsal Nail Plate™, Anatomical** is substantially equivalent to the predicate Dorsal Nail Plate in regards to the intended use, materials, biocompatibility, and overall performance characteristics. The equivalence was confirmed through pre-clinical testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Mr. Ernesto Hernandez
Vice President RA/QA
Hand Innovations, LLC
8905 SW 87th Avenue, Suite 220
Miami, Florida 33176

Re: K052248
Trade/Device Name: Dorsal Nail Plate™, Anatomical
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: HRS
Dated: August 16, 2005
Received: August 18, 2005

Dear Mr. Hernandez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K052248

Device Name: **Dorsal Nail Plate™, Anatomical**

Indications for Use Statement

The **Dorsal Nail Plate™, Anatomical** is intended for the fixation of fractures and osteotomies involving the distal Radius.

Prescription Use___√____ OR Over-The-Counter Use_____

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K052248